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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SNEDDEN, SHERIDAN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,363	MOCHLY-ROSEN, DARIA	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *8 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-18 and 20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-26, drawn to a method of reducing injury to a cell or tissue by administration of the peptide, classified in class 514, subclass 2.

2. Invention I is directed to patentably distinct and/or independent peptides (or use thereof). Absent factual statement/evidence to the contrary, each different peptide sequence is considered distinct and/or independent, one from the other on the basis of physical, chemical and biological properties and function(s). Thus, an election under 35 USC 121 is required as to the elected peptide (by SEQ ID NO). This selection of the peptide (and/or the polynucleotides encoding the peptide) by SEQ ID NO is not a species election.

3. During a telephone conversation with Judith Mohr on March 11, 2003 a provisional election was made with traverse to prosecute the invention of I, claims 1-26 with the additional election of SEQ ID NO: 2. Affirmation of this election must be made by applicant in replying to this Office action. All other patentably distinct and/or independent peptides not defined by the sequence of SEQ ID NO: 2 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 8 and 19 are not directed to SEQ ID NO: 2. Claims 8 and 19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Claims 1-7, 9-18 and 20-26 are under examination.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 2, 3, 7, 11, 12, 13, 18, and 22-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over of claims 10, 11 and 12 of prior U.S. Patent No. 6,165,977 (IDS). Although the conflicting claims are not identical,

they are not patentably distinct from each other because the they relate to the same subject matter taught in Patent '997 and fail to broaden the breath of coverage.

Claims 10, 11 and 12 of Patent '977 are directed to a method for reducing ischemic injury to a cell exposed to hypoxic conditions. In the method, a pharmaceutically-effective dose of a peptide of SEQ ID NO: 6, which is 100% identical to the peptide of SEQ ID NO: 2 of the instant application, is delivered to the cardiac cells of a patient in need of treatment. In the claims, Patent '997 recite a method of reducing ischemic injury to a cell exposed to hypoxia conditions, wherein the administration occurs prior to exposing the cell to the ishemic or hypoxic condition (see claim 10; regarding claims 1 and 2). Patent '997 teaches the administration of a peptide 100% identical to the peptide of SEQ ID NO: 2 (see claims 11, 12 and SEQ ID NO: 6, regarding claim 7 and 18). The administration of the peptide would have occurred 1-180 minutes prior to exposure to hypoxic conditions (see column 18, line 66 and Example 4; regarding claim 3). As the method of claim 10 of Patent '997 is directed to reducing the injury to a cell, the scope of the claim would include the administration to a tissue (in vivo or ex vivo) as recited in claims 12, 13, 23 and 24, as a tissue is necessarily a collection of cells. Patent '997 teach the multiple routes of administration as recited in claims 11 and 22 of the instant application (see column 16, lines 40-50). As patent '997 teach the intracoronary administration of the peptide, administration to an intact heart is taught (see column 16, lines 40-50; regarding claims 24-26).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 9, 10, 12-14, 18, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorn *et al.* (IDS). Dorn *et al.* teach a composition of a psi-epsilon-RACK peptide (HDAPIGYD) identical to SEQ ID NO: 2. Dorn *et al.* teach that the psi-epsilon-RACK peptide caused cardio-protection from ischemia (regarding claims 1 and 7). The study of Dorn *et al.* was conducted by prior administration or expression of the psi-epsilon-RACK peptide to cardiac myocyte cells or whole hearts *ex vivo* that have undergone ischemic exposure for 30 minutes (see Experimental Procedures, pages 12798-99; regarding claims 1-3, 7, 12-14, 18, 23 and 25). Additionally, Dorn *et al.* teach an Antennapedia carrier peptide identical of SEQ ID NO: 3 (see Experimental Procedures; regarding claim 9 and 10). Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 9-18 and 20-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Liang *et al.* (US Patent 6,329,349) in view of Dorn *et al.* (IDS).

Liang *et al.* teach reducing ischemic injury of the heart via sequential administration cardioprotective agents (see column 2, lines 10-35). These methods entail the administration of

cardioprotective agents to a patient prior to surgical treatment followed by administration of a second cardioprotective agent to potentiate the cardioprotective effect. This second cardioprotective agent is delivered to the patient either before, during or after surgery. Alternatively, the second cardioprotective agent may be administered continuously throughout all of these periods (see column 2, lines 10-22; regarding claims 1-6 and 12-17). The cardioprotective agents are delivered to the patient, and therefore to the cells and tissue, by direct perfusion of the organ or by intravenous administration (regarding claims 11, 22, 24, 25 and 26). Liang *et al.* also suggest intracoronary administration of cardioprotective agents (see column 1, lines 42-46, and reference 1 therein; regarding claim 26). Figure 2 shows that the period of ischemia was 90 minutes (regarding claims 3, 5, 14 and 16). Therefore, Liang *et al.* teaches all of the method steps of the present invention, however, does not teach the use of psi-epsilon-RACK peptides as cardioprotective agents.

Dorn *et al.* teach a composition of a psi-epsilon-RACK peptide (HDAPIGYD) identical to SEQ ID NO: 2. Dorn *et al.* teach that the psi-epsilon-RACK peptide caused cardio-protection from ischemia (regarding claims 1 and 7). The study of Dorn *et al.* was conducted by prior administration or expression of the psi-epsilon-RACK peptide to cardiac myocyte cells or whole hearts *ex vivo* that have undergone ischemic exposure for 30 minutes (see Experimental Procedures, pages 12798-99; regarding claims 1-3, 7, 12-14, 18, 23 and 25). Additionally, Dorn *et al.* teach an Antennapedia carrier peptide identical of SEQ ID NO: 3 (see Experimental Procedures; regarding claim 9 and 10). Dorn *et al.* do not teach the administration of the above cardioprotective peptide after or during the exposure to a cell or tissue (regarding claims 4-6 and 15-17). Additionally, Dorn *et al.* do not teach in vivo administration by the routes consisting or

intravenous, intracoronary, parenterally, subcutaneous, inhalation, intranasal, sublingual, mucosal, or transdermal administration of the above cardioprotective peptide (regarding claims 11, 22, 24, and 26).

Taken together the above references teach the administration of the cardioprotective psi-epsilon-RACK peptide or SEQ ID NO: 2 linked to the Antennapedia carrier peptide for reducing injury to a cell using the method steps recited in the claims of the present invention. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to utilize the psi-epsilon-RACK peptide (Dorn *et al.*) in the method of reducing ischemic injury of the heart via the sequential administration of cardioprotective agents as taught by Liang *et al.* As the psi-epsolon-RACK peptide of the instant invention and agents of Liang *et al.* possess the identical cardioprotective effect, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to substitute one for another. A person of ordinary skill in the art would have been motivated and expected success to make the above substitution as a synergistic effect would have been observed using a combination of cardioprotective agents that function via different mechanisms, as suggested by Liang *et al.* Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
March 24, 2003
SKS

Christopher S. F. Low
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